## REMARKS

Prior to the present amendment, claims 1-11 and 15- 25 were under consideration. Claims 12-14 and 26-31 were previously withdrawn from consideration as being drawn to a nonelected invention following a restriction requirement. By this amendment, applicants have canceled claims 1-31and have added new claims 32-46. Accordingly, claims 32-46 are currently pending.

Pursuant to 37 CFR §§ 1.821-1.825, applicants are electronically submitting herewith a Sequence Listing as a text file (.txt). The content of the sequence listing does not extend beyond the original disclosure and does not include new matter.

**Objections to the Specification**

On page 2 of the office action, the examiner objected to the specification for not providing sequence identifiers to two sequences located on page 20 of the specification as filed.

Applicants have accorded sequence identification numbers to the two sequences and submit herewith a new, complete sequence listing in compliance with 37 C.F.R § §1.821(c), (e) and (f). Applicants have also amended page 20 of the specification to include the new sequence identification numbers.

Next, the examiner objected to the specification for are not properly identifying trademarks and for a misspelling of the term "amino acid."

Applicants have undertaken to properly identify trademarks, such as TRIPURE™ and LIPOFECTAMINE PLUS™, and to correct any misspelling of the term "amino acid." Accordingly, applicants respectfully requests that the examiner reconsider and withdraw the objections.

**Objections to the Claims**

On page 3 of the office action, the examiner objected to claims 2, 4, and 6 for misspelling the term "amino acid."

As stated above, applicants have canceled claims 1-11 and 15-25. New claims 32- 46 do not recite the misspelled term. Accordingly, applicants respectfully requests that the examiner reconsider and withdraw the objections.

**Rejection under 35 U.S.C. § 112, second paragraph– indefiniteness**

On page 4 of the office action, the examiner rejects claims 1-11 and 15-25 as being indefinite. In particular, the examiner rejects various combinations of the claims as being indefinite for reciting the following:

a. "of the monomeric scFv type obtained from the RNA extracted from the hybridoma producing Mab CB/ior-CEA.1";

b. "of the divalent (diabody) scFv type obtained from the RNA extracted from the hybridoma producing Mab CB/ior-CEA.1";

c. "such antigen";

d. "dependent on the conservation of *its* glycosylation";

e. "or fused to biologically or biochemically active domains"

f. "other scFv variants"

g. "in an insect or from mammalian transfected cells"

h. "the detectable by other method"

i. "linked or not to cells"

In response, applicants have canceled claims 1-11 and 15-25. New claims 32-46 do not recite the allegedly indefinite phrases above. Accordingly, applicants respectfully request the examiner to reconsider and withdraw the rejection.

**Rejection under 35 U.S.C. § 112, first paragraph– enablement**

**a. Biological Deposit Requirement**

On page 6 of the office action, the examiner rejects claims 1, 3, 5, 7-11, 15, 16, 18, 20, 22, and 24 because the specification allegedly does not provide evidence that the claimed biological materials are known and readily available to the public and reproducible from the written description.

Applicants note that the examiner did not reject claims 2, 4, and 6. Claims 2, 4, and 6 recite antibody fragments containing amino acid sequences as set forth in SEQ ID NO: 16 and/or 17.

In response to the examiner's rejection, applicants have canceled claims 1, 3, 5, 7-11, 15, 16, 18, 20, 22, and 24. New claims 32-46 recite an amino acid sequence as set forth in SEQ ID NO.: 16 and/or SEQ ID NO: 17, which are known and readily available to the public and reproducible from the written description. Accordingly, applicants respectfully request the examiner to reconsider and withdraw the rejection.

**b. Scope of Enablement**

On page 9 of the office action, the examiner rejects claims 9, 20, and 21 because the specification allegedly does not reasonably provide enablement for a pharmaceutical composition to treat any human with any CEA-expressing tumor. According to the examiner, one skilled in the art could not have practiced treating any human CEA-expressing tumor with a pharmaceutically formulated monomeric CEA scFv, dimeric CEA scFv, or antibody fragments containing the VH/VL of a CB/ior-CEA.1 antibody for targeted delivery of the molecule as an intended therapeutic.

The examiner concedes, however, that the specification enables a pharmaceutical composition comprising antibodies derived from CB/ior-CEA.1 mAb, or the monomeric scFv

(SEQ ID NO: 16), the diabody scFv (SEQ ID NO: 17) and fragment thereof, with the intended use of treating a CEA-expressing tumor.

In response, applicants have canceled claims 9, 20, and 21. New claims 36 and 43 focus on a pharmaceutical composition containing a recited sequence that the examiner deems enabled.

For the foregoing reasons, applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

**Rejection under 35 U.S.C. § 103 in view of Tormo *et al.*, Freyre *et al.*, and Holliger *et al.***

On page 16 of the office action, the examiner rejects claims 1, 3, 5-8, 10, 11, 15-19, and 22-25 as being allegedly obvious over Tormo, et al. (*APMIS*, 97(12): 1073-80 (1989)), in view of Freyre, et al. (*J. Biotechnol.* 76:157-163 (2000)), as evidenced by Ayala, et al. (*Conf. on Plant-Made Pharmaceuticals 2005*; Abstract), in further view of Holliger, et al. (*PNAS*, 90: 6444-6448 (1993)).

According to the examiner, Tormo et al. disclose a CB/ior-CEA.1 mAb-producing hybridoma and a CB/ior-CEA.1 murine mAb. The examiner acknowledges that Tormo et al. do not disclose antibody constructs such as a monomeric and diabody scFvs using the VH and VL domains from the parent antibody.

The examiner cites Freyre et al. for their alleged disclosure of a scFv that was produced using the VH and VL of CB/ior-CEA.1, but had significantly reduced antigen binding capability.

The examiner cites Holliger et al. for their alleged disclosure of an alternative means for producing scFv forms.

According to the examiner, it would have been obvious to combine the techniques of Tormo et al, Freyre et al, and Holliger et al. to obtain an improved antibody fragment having at least the binding properties of CB/ior-CEA.1. antibody.

In response, applicants have canceled claims 1, 3, 5-8, 10, 11, 15-19, and 22-25. New claims 32-46 recite antibody fragments containing a sequence that is not disclosed or suggested in any of the cited references, individually or in combination. In addition, applicants note that the examiner did not reject claims 2 and 4 in view of the cited references. Claims 2 and 4 recite antibody fragments containing amino acid sequences as set forth in SEQ ID NO: 16 or 17.

For the foregoing reasons, applicants respectfully request that the rejection under 35 U.S.C. § 103 be reconsidered and withdrawn.

**Conclusion**

In view of the foregoing amendments and remarks, entry of the amendments to the claims and favorable thereof are respectfully requested.

If any additional fees are due or any overpayment has been made in connection with filing this paper, please charge or credit our Deposit Account No. 08-2461 for such sum. If the examiner has any questions or concerns regarding this amendment, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/anna c. chau
Anna C. Chau
Registration No.: 54,637
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550
ACC:jp

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